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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,763	11/20/2003	Ron L. Hale	00064.01R	3281

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,763	HALE ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments over the 35 USC 103 rejection over Caruso have been considered. In particular Applicants argue that Caruso does not teach or suggest a composition comprising a dose of less than 9 mg prochlorperazine and that the present inventors describe in the specification that a low dose of prochlorperazine is effective in treating migraine. Applicants further argue that claim 33 requires that the composition comprise prochlorperazine as the only active ingredient. In response to the above arguments, it is noted that Caruso does not exemplify a particular dose of prochlorperazine; therefore, it would be obvious to vary and/or optimize the amount of prochlorperazine in the composition to provide a composition having the desired potentiation of the anti-migraine drug. It is furthermore noted that Caruso does not meet the new claim limitation of claim 33 because Caruso does not teach compositions with prochlorperazine alone. Therefore the rejection over claim 33 in particular is withdrawn.

Applicant's arguments over the 35 USC 103 rejection over Caruso in view of Howell et al. have been considered. In particular, Applicants argue that there is no prima facie case of obviousness. In response to this argument, it is noted that Howell was used to address the limitation that there are inhalation devices that are capable of forming a condensation aerosol. Therefore, each and every claim element has been addressed.

Due to Applicants amendments to the claims, the 35 USC 103 rejection over Caruso in view of Hendricks et al. is hereby withdrawn.

Applicants argue over the Double Patenting rejections over Application 11/346,548, U.S. Patents 7,090,830; 7,078,020; and Application Numbers 10/633,877, 10/633,876, 11/248,598. In particular, Applicants argue the present claims and the claims of copending Application 11/346,548 are not coextensive in scope. In response to this, it is noted that the claim of Application 11/346,548 are drawn to a kit comprising a phenothiazine antipsychotic (including prochlorperazine) in an inhalation delivery device. Further the claims are drawn to a dose of 1 mg to 18 mg of prochlorperazine which overlaps that of the present invention. Therefore the inventions are obvious over the other and the rejection is maintained.

Applicants argue that the rejection over US Patents 7,090,830 and 7,078,020 should be withdrawn because the present claims have been amended to recite that the device is for delivering the composition to the patient. In response to this, it is noted that the present claims are drawn to a kit that comprises prochlorperazine and the claims of US Patents 7,090,830 and 7,078,020 are also drawn to a kit that comprises prochlorperazine which is also for delivering a condensation aerosol. Accordingly, the claims remain obvious over the other and the rejection is maintained.

Applicants argue that the rejection over Applications 10/633,876, 11/488,932, and 11/248,598 should be withdrawn because the claims have been amended to recite a device for delivering the composition to a patient and the claims of Application 10/633,876 are drawn to an assembly for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery where the drug can be prochloroperazine, the claims for Application 11/488,932 are drawn to a kit for aerosol drug delivery having

a device for dispensing aerosol where the drug is prochlorperazine and the claims for Application 11/248,598 are drawn to a particular type of inhalation device having a dosage of a drug where the drug can be prochlorperazine. All the applications are drawn to an inhalation device, which is obviously for administration to a patient, of prochlorperazine; therefore, all of the applications are obvious over the present application. Further, varying and/or optimizing the dose of prochlorperazine is an obvious modification.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-39 rejected under 35 U.S.C. 102(e) as being anticipated by Rabinowitz et al. (US Pg-Pub 2004/0009128).

Rabinowitz et al. teaches drug amine containing aerosols delivered using an inhalation device (meeting the limitations of claims 32 and 38; paragraph 0170). It is also taught that the aerosol can be a condensation aerosol (meeting the limitation of claim 39; paragraph 0170). Table 1 gives examples of drug amines that are volatilized according to the invention, in which prochlorperazine is included at a dose of 5 mg

(meeting the limitation of dose of prochlorperazine listed in claims 32, 35-37). Further, Examples 1 and 2 give the general procedure of volatilizing drug amines in which it is shown that the drug amine is the only active ingredient in the device, as is also evidenced by Table 1. Excipients are further taught to include water, ethanol, propylene glycol and glycerol (meeting the limitation of claim 34; paragraph 0164).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32, 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Frank S. Caruso, issued April 6, 1999.

Caruso teaches methods and compositions for the treatment of migraine headaches. Caruso teaches that preferred compositions include an anti-migraine agent in combination with a NMDA receptor blocker (see column 2, lines 25-35, in particular). Caruso teaches that compounds that also assist in blocking the consequences of NMDA receptor activation, and that are thus also suitable for use in the anti-migraine composition in addition to or in place of the NMDA receptor blocker include phenothiazines, such as prochlorperazine (see column 3, lines 53- 65, column 4, lines

10-35 and 49-65, and column 5, lines 9-20, in particular). Thus, Caruso teaches providing the antipsychotic prochlorperazine as recited in claims 32, and 35-37 for the treatment of migraine headaches.

Caruso does not specifically exemplify a "kit" having the phenothiazine antipsychotic and an inhalation delivery device, as recited in claim 32.

However, Caruso does teach that such anti-migraine compositions can be therapeutically delivered via inhalation means, such as via a pressurized pack or a nebulizer (see column 6, lines 62-66, in particular). Caruso also exemplifies an anti-migraine composition in inhalation dosage form (see Example 12, in particular).

Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the anti-migraine composition having prochlorperazine via inhalation means, and thus to provide a "kit" having the composition and an inhalation device, such as a pressurized aerosol pack or nebulizer, because Caruso teaches the antipsychotic phenothiazine is suitable for the treatment of migraines, and also teaches that anti-migraine compositions can be therapeutically administered via inhalation. Thus, one of ordinary skill in the art would have been motivated to provide a "kit" having the anti-migraine composition containing prochlorperazine and an inhalation delivery device, with the expectation of providing a device suitable for the therapeutic treatment of migraines. Accordingly, claims 32 and 35-37 are obvious over the teachings of Caruso.

Regarding claim 35, it is noted that Caruso teaches that the potentiating agent must be present in an amount that potentiates the effectiveness of the anti-migraine

drug (see column 5, lines 38-60, in particular). Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phenothiazine antipsychotic provided in the composition, according to the guidance provided by Caruso, to provide a composition having desired potentiation of the anti-migraine drug. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955).

Regarding claim 36, it is noted that Caruso teaches that capsules and cartridges can be formulated for use in inhalers containing the composition (see column 7, lines 1-10, in particular). Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phenothiazine antipsychotic provided in a capsule or cartridge composition, and to provide more than one such capsule or cartridge with different dosages, according to the guidance provided by Caruso, to provide a desired antimigraine treatment regimen with the inhalation device. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955).

Claims 38-39 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,891,885 to Frank S. Caruso, issued April 6, 1999, as applied to claims 32-

36 above, and further in view of U.S. Patent No. 5,743,251 to Howell et al, issued April 28, 1998.

Caruso is applied as discussed above, and renders obvious a "kit" having an inhalation device and an anti-migraine composition containing prochlorperazine.

Caruso does not specifically teach that the inhalation device is capable of producing a condensation aerosol, as recited in claim 39.

Howell et al. teaches an aerosol generating apparatus suitable for inhalation administration of pharmaceutical compositions (see abstract and column 1, lines 1-35, in particular). Howell et al. teaches that the particular apparatus taught therein is capable of volatilizing a material, which then condenses to form an aerosol (see abstract, in particular). Accordingly, Howell et al. is considered to teach an inhalation device capable of forming a condensation aerosol for therapeutic administration.

Accordingly, it is considered that one of ordinary skill in the art at the time of the invention would have been motivated to provide the condensed aerosol forming inhalation device of Howell et al. in the "kit" of Caruso, because Caruso teaches that the anti-migraine compositions can be administered via inhalation, in general, and Howell et al. teaches a device that is suitable for the inhalation administration of therapeutic compositions. Thus, one of ordinary skill in the art would have been motivated to provide the condensed aerosol forming inhalation device of Howell et al. as the inhalation device for the administration of the anti-migraine composition of Caruso, with the expectation of success in providing a device capable of delivering the anti-migraine composition via inhalation to effect treatment of migraines.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See Millerv. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438,164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 32-38 are provisionally rejected for statutory type double patenting over claims 32-38 of U.S. Patent Application Serial No. 11/346,548 as published in U.S. Patent Application Publication No. 2006/0193788 to Hale et al, published August 31, 2006. The instant and published claims are identical, and thus the instant claims are rejected for statutory type double patenting over the conflicting claims.

This is a provisional statutory-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438,164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA

1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 27 of U.S. Patent No. 7,090,830 to Hale et al, issued August 15, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a kit having a particular inhalation device and a drug, where the drug can be prochlorperazine, and phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the patented claim, and are not patentably distinct over claim 27 of U.S. Patent No. 7,090,830.

Claims 32-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-27 and 43-62 of U.S. Patent No. 7,078,020 to Rabinowitz et al, issued July 18, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a kit having a particular inhalation device and a drug, where the drug can be prochlorperazine, and phenothiazine antipsychotic.

Accordingly, the instant claims are obvious over the patented claims, and are not patentably distinct over claims 20-27 and 43-62 of U.S. Patent No. 7,078,020.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/633,877 as published in U.S. Patent Application Publication No. 2007/0031340 to Hale et al, published February 8, 2007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to an article for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug where the drug can be prochlorperazine, a phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over claim 9 of copending U.S. Patent Application No. 10/633,877.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/633,876 as published in U.S. Patent Application Publication No. 2007/0028916 to Hale et al., published February 8, 2007. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

instant claims are drawn to a kit having an inhalation delivery device and prochlorperazine, and the conflicting claims are drawn to an assembly for aerosol delivery having a substrate suitable for vaporization of a drug for aerosol delivery, and a drug, where the drug can be prochlorperazine, a phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claims and are not patentably distinct over claim 26 of co-pending Application No. 10/633,876.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 32-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 11/248,598 as published in U.S. Patent Application Publication No. 2006/0120962 to Rabinowitz et al, published June 8, 2006. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a kit having an inhalation delivery device and phenothiazine antipsychotic, and the conflicting claims are drawn to a particular type of inhalation device having a dosage of drug, where the drug can be prochlorperazine, and phenothiazine antipsychotic. Accordingly, the instant claims are obvious over the published claim, and are not patentably distinct over claim 9 of copending Application No. 11/248,598.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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